

MEDICATION GUIDE

LOTRONEX® (LOW-trah-nex) Tablets alosetron hydrochloride

Read this information carefully before you start taking LOTRONEX Tablets. Read the information you get with LOTRONEX each time you refill your prescription. There may be new information. This information does not take the place of talking with your doctor.

What is the most important information I should know about LOTRONEX?

LOTRONEX is used to help women who have irritable bowel syndrome (IBS) with diarrhea as their main symptom (diarrhea-predominant IBS). **Women who have constipation as their main IBS symptom should not use LOTRONEX.** LOTRONEX has not been shown to help men.

IBS generally does not result in a need for bowel surgery (operation). A few patients taking LOTRONEX can develop intestinal side effects serious enough to need hospitalization and possibly surgery. **Before starting LOTRONEX, discuss with your doctor how troublesome your IBS symptoms are, the possible benefits of LOTRONEX, and its possible side effects to decide if LOTRONEX is right for you.**

Possible serious side effects of LOTRONEX include:

1. Constipation

LOTRONEX may result in constipation that infrequently may be serious enough to block movement of stools through the intestines. In a few women, this may lead to hospitalization and possibly surgery.

- **Do not start taking LOTRONEX if you are constipated.**
- **If you get constipated while taking LOTRONEX call your doctor right away. If you develop any of the following symptoms while waiting to talk to your doctor, stop taking LOTRONEX:**
 - **severe constipation**
 - **worsening or bothersome constipation with increased abdominal discomfort**

Do not start taking LOTRONEX again until you talk to your doctor.

2. Ischemic colitis

Some patients (about 1 in 700) developed ischemic colitis while using LOTRONEX. Ischemic colitis is a serious condition caused by reduced blood flow to the intestines. This condition may

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need hospitalization and possibly surgery. **Stop using LOTRONEX and call your doctor right away** if you have any of these signs of ischemic colitis:

- new or worsening abdominal (lower stomach area) pain
- bloody diarrhea or blood in the stool (bowel movements)

What is LOTRONEX?

LOTRONEX is a prescription medicine used to treat IBS in women who have diarrhea as their main symptom (diarrhea-predominant). LOTRONEX has not been shown to help men with IBS.

IBS is also called irritable colon and spastic colon. IBS causes lower abdominal (stomach) pain and discomfort, urgency (a sudden need to have a bowel movement), and irregular bowel habits, such as diarrhea or constipation. It is not clear why people develop IBS. Some scientists think IBS is caused by an overreaction to a body chemical called serotonin. This may cause patients' intestines to be overactive. IBS can be constipation-predominant, diarrhea-predominant, or can involve constipation and diarrhea. LOTRONEX is only for women with diarrhea-predominant IBS.

LOTRONEX does not help everyone. For those who get relief, LOTRONEX helps reduce IBS-related lower abdominal pain, abdominal discomfort, urgency and diarrhea. You may get relief of some or all of your symptoms after 1 to 4 weeks of use. If LOTRONEX does not reduce your symptoms after 4 weeks, stop using it and tell your doctor.

LOTRONEX does not cure IBS. When you stop taking LOTRONEX, your IBS symptoms will probably return within 1 week.

Who should not take LOTRONEX?

LOTRONEX is not right for everyone. It is only for women with troublesome diarrhea-predominant IBS.

1. Do not **start** taking LOTRONEX if you are constipated
2. Do not **ever** take LOTRONEX if you
 - are constipated most of the time
 - have ever had severe constipation or a serious problem from constipation
 - have ever had ischemic colitis
 - have ever had Crohn's Disease or ulcerative colitis
 - have active diverticulitis
 - are allergic to LOTRONEX or any of its ingredients (see list of ingredients at the end of this Medication Guide).

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If you take LOTRONEX under these conditions, you increase your risk of getting serious side effects.

Tell your doctor if you are pregnant, planning to get pregnant, breast feeding, or taking or planning to take other prescription or non-prescription medicines.

How should I take LOTRONEX?

Take LOTRONEX exactly as your doctor prescribes it. You can take LOTRONEX with or without food. If you miss a dose of LOTRONEX, do not double the next dose. Wait until the next scheduled dosing time and take your normal dose.

What are the possible side effects of LOTRONEX?

Constipation is the most common side effect of LOTRONEX. A few patients may develop serious intestinal side effects. A description of these side effects, how to identify them, and what action to take if you get them, is in the first section of this Medication Guide, “What is the most important information I should know about LOTRONEX?” Refer to the information about constipation and ischemic colitis in that section.

These are not all the side effects of LOTRONEX. Your doctor or pharmacist can give you a more complete list.

General advice about prescription medicines

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you have any concerns about LOTRONEX, ask your doctor. Your doctor or pharmacist can give you information about LOTRONEX that was written for health care professionals. Do not use LOTRONEX for a condition for which it was not prescribed. Do not share LOTRONEX with other people.

Ingredients: alosetron hydrochloride, lactose (anhydrous), magnesium stearate, microcrystalline cellulose, and pregelatinized starch. The blue film-coat contains hydroxypropyl methylcellulose, titanium dioxide, triacetin, and indigo carmine.

This Medication Guide has been approved by the US Food and Drug Administration.

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